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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,035	12/05/2003	Alain F. Carpentier	ECV-5413CIP2CON1	2075
30452 7590 02/14/2008 EDWARDS LIFESCIENCES CORPORATION LEGAL DEPARTMENT ONE EDWARDS WAY IRVINE, CA 92614			EXAMINER WALKER, AMANDA H	
			ART UNIT 3774	PAPER NUMBER
			MAIL DATE 02/14/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/729,035	Applicant(s) CARPENTIER ET AL. <span style="float: right;">CT</span>	
	Examiner AMANDA H. WALKER	Art Unit 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 09 April 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-10,13-18,21-23 and 31-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 31-41 is/are allowed.
- 6) ☒ Claim(s) 1-10,13-18,21-23 and 42-45 is/are rejected.
- 7) ☒ Claim(s) 43 and 45 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some    \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of the Claims***

Claims 1, 4, and 13 have been amended. Claims 42-45 have been newly added. Accordingly, claims 1-10, 13-18, 21-23, and 31-45 are pending for consideration.

### ***Claim Objections***

New claims 43 and 45 are objected to for depending from cancelled base claims.

### ***Claim Rejections - 35 USC § 103***

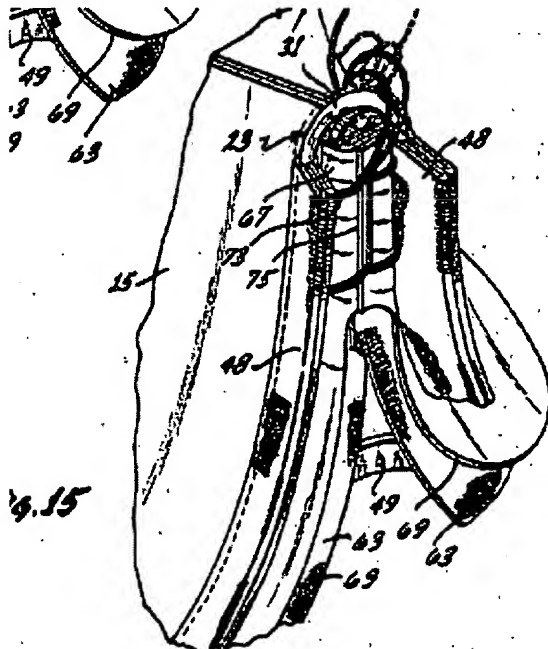
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 6-10, 13-18, 22-23, and 42-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lane (United States Patent Number 4501030) in view of Bessler et al. (United States Patent Number 5,855,601).

The claim as broadly worded does not distinguish over the band 48 as illustrated in figure 15 of Lane. The claims as worded are readable on the intermediate product shown in the figure below. While the frame of Lane is not specifically identified as being made of nitinol, Bessler et al teaches forming frames from a variety of materials including nitinol. To form the frame of nitinol to ensure proper final configuration in the body would have been obvious from the teachings of Bessler et al.



Claim 2, see the three stent cusps and commissures.

Claims 3 and 4, see orientation of stent, commissures and the angled band.

Claims 6 and 7, see fabric covering the stent in the figures. Note the claims do not preclude the band forming the fabric covering the stent.

Claims 9-10, see band 48 attached to stent.

Claims 13-19, 22 and 23, see rejection to corresponding claims supra.

Regarding new claims 42-45: The nitinol frame taught by Bessler et al. is both made of nitinol and is inherently flexible.

#### ***Allowable Subject Matter***

Claims 31-41 are allowable over the art of record.

Claims 5 and 21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Response to Arguments***

Applicant's arguments filed on 9-4-2007 have been fully considered but they are not persuasive.

Applicant argues that one of skill in the art would not substitute a flexible material such as Nitinol for the frame of Lane. However, Lane teaches using various

biocompatible materials, such as suitable metals and plastics, of which the Nitinol taught by Bessler is a member. Furthermore, Lane does not teach that the material must be rigid. To the contrary, any metal or plastic wire of that size is going to have a degree of flexibility.

Applicant also argues that the intermediate product step taught by Lane is not applicable to the claims toward the assembled valve. However, the band 48 taught in the intermediate step of assembly (FIG. 15) is capable of being sutured to the tissue.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### ***Correspondence***

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda H. Walker whose telephone number is (571)270-3296. The examiner can normally be reached on 8-5, M-Th, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AHW  
1-4-07

  
**CORRINE McDERMOTT**  
**SUPERVISORY PATENT EXAMINER**  
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